

DIVISION OF OTC DRUG PRODUCTS  
CENTER FOR DRUG EVALUATION AND RESEARCH  
ANNOUNCEMENT OF OTC DRUG FEEDBACK MEETING

BETWEEN: Representatives of FDA

and

Members of the European Manufacturers Coalition  
(List of attendees pending)

TOPIC: Time frames for issuance of the foreign marketing  
proposed and final rule; review of foreign marketed sunscreen  
ingredients; and a proposal for a third-party review pilot  
program.

DATE: October 28, 1998

TIME: 12:00 p.m.

LOCATION: S-200A  
9201 Corp. Blvd.  
Rockville, MD

Pursuant to the agency's policy statement published in the FEDERAL REGISTER of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050) and February 4, 1985 (50 FR 4916), which includes provisions for agency meetings with industry or other interested persons, this feedback meeting is being announced.

All feedback meetings are open to the public and no prior reservation is necessary. For further information or to reconfirm that the meeting has not been rescheduled or canceled, call Ms. Valerie Miguete, 301-827-2247.

ATTENTION: JENNIE BUTLER  
cc: Docket No. 80N-0295  
DATE FORWARDED: \_\_\_\_\_

80N-0295

mm/06

**Attendees to the October 28, 1998 Feedback Meeting With Industry re OTC Sunscreen Monograph Review and OTC Active Ingredients; Third Party Proposal Sent on 9/18:**

**FDA:**

Robert Delap, M.D., Director, Office of Drug Evaluation V  
Debra Bowen, M.D., Deputy Director, Office of Drug Evaluation V  
Jane Axelrad, Associate Director for Policy, Office of the Director, CDER  
Gerald Rachanow, Regulatory Counsel, HFD-560  
John Lipnicki, Team Leader, HFD-560  
Donald Dobbs, Interdisciplinary Scientist/Biologist, HFD-560  
Kay Freeman, Microbiologist, HFD-560  
Sakineh Walther, Project Manager, HFD-560  
Babette Merritt, Project Manager, HFD-560

**Sponsors:**

Dr. Rolf-Dieter Reinhardt (BASF-AG (Ludwigshafen, Germany))  
Ina Hofgen-Mueller (Merck KgaA (Darmstadt, Germany))  
James Smith and/or Carl Harris (Haarmann & Reimer (Bayer), U.S.)  
Kathy Sanzo (Morgan, Lewis and Bockius-Counsel for BASF-AG)  
Robert G. Pinco/Mark M. Yacura/Mary Johnson (Akin, Gump, Strauss, Hauer & Feld)  
Doug Manning, E.M. Industries